

GUIDELINES FOR REVIEWER'S WRITTEN COMMENTS
NIDDK SMALL GRANT (R03) PROGRAM FOR K08 OR K23 RECIPIENTS

The R03 award is intended to provide additional research support as the K08 or K23 recipient transitions to independent investigator status. The scientific directions of the proposed project may not have been anticipated by the project originally outlined in the K08 or K23 application, but instead may reflect the emerging research focus of the investigator as a consequence of that research. Refer to the NIH Guide announcements ([PAR-04-070](#), 3/3/04) for more detail about the award. The format outlined below should be followed in preparing your comments for each R03 application assigned to you. Include additional headings when they seem appropriate to the review.

FOR PRIMARY AND SECONDARY REVIEWERS:

RESUME: In a brief paragraph, indicate the major strengths and weaknesses of the proposed program as a means of enhancing the investigator's research career and how these factors determine your overall merit rating of the application.

CRITIQUE: Address each of the following five criteria as separate sections within the context of the stage of the investigator's career.

DISCUSSANTS The written critique for a discussant review may be brief; all aspects of the five review criteria do not need to be specifically addressed. A brief paragraph highlighting the strengths and weaknesses of the application or bulleted lists of strengths and weaknesses are both examples of acceptable critiques. If you prefer to prepare a full critique equivalent to a primary or secondary review, you also have that option.

1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

(2) Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

(4) Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? Do not include descriptive biographical information.

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support? Do not describe available facilities and equipment.

CAREER DEVELOPMENT PLAN: Evaluate the accomplishments of the investigator with respect to the original research goals of the K08 or K23 grant and the potential of the project to help prepare the investigator for full independence. Recall that the proposed project may represent the evolution of the individual's own research focus.

MENTOR: Assess the relationship of the mentor and his/her evaluation of the investigator's progress under the K08 or K23 grant.

ACTION: The application may be recommended for no further consideration, deferred in order to obtain additional information, or given a priority score. If the application is to be scored, indicate the level of scientific merit using the adjectival scale.

BUDGET: Comment on the appropriateness and justification of the budget request within the context of the goal of the award. Up to \$50,000 per year is allowed for salary, tuition, fees, and books related to career development; research expenses such as supplies, equipment, and technical personnel; travel to research meetings or training; and statistical services including personnel and computer time.

OTHER CONSIDERATIONS: If these matters affect the assessment of the scientific merit of the application, they will be considered as part of the critique and the overall score.

Involvement of Human Subjects: Explain concerns regarding the proposed use of human subjects, including any possible physical, psychological, or social injury individuals might experience while participating as subjects in the research. Indicate whether their rights and welfare will be protected adequately or whether they may be subjected to ethically questionable procedures. Determine if an appropriate balance of gender and minority representation in the study population will be sought, if this is scientifically acceptable, and justify the gender and minority codes to be assigned. Determine whether children have been included in the research and if their inclusion or exclusion has been explained adequately to justify the code to be assigned.

Animal Welfare: If animals are to be used in the project, discuss if their use is justified and if they will be given proper care and humane treatment so that they will not suffer unnecessary discomfort, pain, or injury.

Model Organism Sharing Plan: All NIH applications that plan to produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state why such sharing is restricted or not possible. Please comment on the adequacy of the sharing plan, taking into consideration the organism, the timeline, and the applicant's decision to distribute the resource or deposit it in a repository. Your assessment of the sharing plan will not be factored into the priority score of the application. Your comments will be captured in an administrative note.

Hazardous Materials and Procedures: Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.